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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,332	04/21/2004	Ana San Gabriel	26099	4229
20529	7590	01/06/2006	EXAMINER	
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/828,332

Applicant(s)

GABRIEL ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/11/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The cancellation of claims 4-6 and the addition of new claims 16-27 have been made of record.

Claims 1-3 and 7-27 are pending. Claims 1-3 and 7-15 are withdrawn.

Claims 16-27 are under examination.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Response to Arguments

Claim Rejections/Objections - Withdrawn

The objection of claims 4-6 for depending from non-elected invention is withdrawn due to Applicant's cancellation of the claims.

The rejection of claims 4-6 under 35 U.S.C. 101 because a DNA that encodes a glutamic acid receptor, is withdrawn due to Applicant's cancellation of the claims.

Applicant's pointing to an unrelated paragraph on page 5, is acknowledged and the paragraph is withdrawn.

The rejection of claims 4-6 are under 35 U.S.C. 112, second paragraph, is withdrawn due to Applicant's cancellation of claims.

Applicant's arguments, see Remarks, filed 10/11/2005, with respect to the rejection(s) of claim(s) 4-6 under 35 U.S.C. 102(b) as being anticipated by Chaudhari et al have been fully considered and are persuasive. Therefore, the rejection has been

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withdrawn. However, upon further consideration, the rejection is maintained in view of Chaudhari et al. for the newly added claims 16 -17, 19-21, 23-25, and 27 for the reasons of record in the previous office action.

Claim Rejections – maintained

The rejection of claims 16 -17, 19-21, 23-25, and 27 under 35 U.S.C. 102(b) as being anticipated by Chaudhari et al. (IDS, Nature neurosci. 3: 113-119, 2000) is maintained for the reasons set forth, supra.

Claims are drawn to a DNA that encodes a brain glutamic acid receptor that has (i) a transmembrane domain, (ii) an intracellular domain common to type 4 metabotropic glutamic acid receptor (mGluR4), (iii) an extracellular domain shorter by about 316 or 327 than mGluR4 (iv) the brain mGluR4 encoding DNA that is hybridizable with the nucleic acid of SEQ ID NO: 6, (v) a cell harboring the DNA in an expressible form, and (vi) a method of producing the receptor protein.

Applicant argues that Chaudhari et al. do not teach the instantly claimed mGluR4 variant and that the Chaudhari's taste-mGluR4 is 20 or 31 amino acids longer than the instantly claimed receptor.

Applicant's arguments have been fully considered but are not found to be persuasive. The specification discloses a DNA that encodes the mGluR4 with SEQ ID NO: 6 which is not disclosed by Chaudhari et al. However, Chaudhari et al disclose that splice variants of their disclosed receptor are possible because multiple promoters may yield mRNAs with distinct 5' exons (pg 118, last paragraph of the left column).

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Therefore, one can identify other variant receptors. They explicitly do not teach expression of variants in rat small and large intestine. However, one skill in the art would have analyzed tissue expression of various variants in different tissues and species for pharmaceutical applications. They teach hybridization of nucleic acids for detecting message expression in various tissues (pages 115-116). They disclose a glutamate receptor variant comprising a transmembrane, an intracellular domain common to type 4 metabotropic receptor, a shorter receptor than a type 4 metabotropic receptor, and a method of expressing the receptor in CHO cells (pages 114, right column through 117). Thus, it meets the limitations of claimed invention.

Claim Rejections - 35 USC § 112-written description

The rejection of claims 16 -17, 19-21, 23-25, and 27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons of record on pages 3-5 of the previous office action mailed on 7/11/2005.

Claims are drawn to a DNA that encodes a brain type 4 glutamic acid receptor that has (i) a transmembrane domain, (ii) an intracellular domain common to mGluR4 (iii) extracellular domain shorter by about 316 or 327 than mGluR4 (iv) the brain mGluR4 encoding DNA that is hybridizable with the nucleic acid of SEQ ID NO: 6, (v) a cell harboring the DNA in an expressible form, and (vi) a method of producing the receptor protein.

Applicant argues that Han et al (IDS, J. Biol. Chem. 274: 1008-10013, 1999) disclose an extracellular domain of mGluR4. Therefore, one skill of the art would be able to identify a common mGluR4 intracellular and extracellular domain.

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Applicant's arguments have been fully considered but are not found to be persuasive.

Han et al, page 10008 right column, disclose that the basic structural domains of mGluRs include a large extracellular amino-terminus domain (ATD), a hydrophobic region containing seven transmembrane domains and an intracellular carboxy terminal domain. They do not teach a common extracellular and intracellular domain for mGluR4. The specification fails to disclose any conserved domain, biological function, disease association or specific functional feature of the polypeptide. The instant specification does not provide specific guidance about common intracellular domain of mGluR4. Further, the specification does not provide any specific guidance on to what residues constitute extracellular domain or intracellular domain of the peptide. In the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed invention.

The specification must provide sufficient distinguishing identifying characteristics for the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the chemical product, or any combination thereof. Therefore, the skilled artisan cannot envision the detailed structure of a DNA that encodes a glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to mGluR4 (iii) extracellular domain shorter by about 316 or 327 than mGluR4, and therefore conception is not achieved until reduction to practice has occurred.

Claim Rejections - 35 USC § 112 first paragraph, enablement

The rejection of claims 16 -17, 19-21, 23-25, and 27 under 35 U.S.C. 112, first paragraph, enablement is maintained for the reasons of record on pages 5-7 of the Office Action mailed on 7/11/2005.

Claims are drawn to a DNA that encodes a glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to type 4 metabotropic glutamic acid receptor (mGluRec), (iii) extracellular domain shorter by about 316 or 327 than type 4 metabotropic glutamic acid receptor, (iv) the brain mGluR4 encoding DNA is hybridizable with the nucleic acid of SEQ ID NO: 6, (v) a cell harboring the DNA, and (vi) a method of producing the receptor protein.

Applicant argues that the cancellation of claims 4-6, and the substitution of these claims with new claims, which are more directed to brain mGluR4 protein with a specific sequence identifier, provides enablement for the instant invention.

Applicant's arguments have been fully considered but are not found to be persuasive. Claims 16 -17, 19-21, 23-25, and 27 are not directed to a specific mGluR4 rather any brain type 4 glutamic acid receptor that has (i) a transmembrane domain, (ii) in intracellular domain common to mGluR4, (iii) extracellular domain shorter by about 316 or 327 than mGluR4. There is no functional limitation, biological function or disease association of the claimed invention. Further, the specification does not provide any specific guidance on to what residues constitute extracellular domain or intracellular domain of the peptide. Therefore, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Objections

Claims 18 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Claim 18 and 26 are free of prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

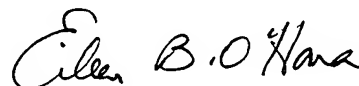
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gyan Chandra, Ph.D.
Art Unit 1646
28 December 2005
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EILEEN B. O'HARA
PATENT EXAMINER